K112934

JAN 2 0 2012

Bio-Medical Research Ltd.

Parkmore Business Park West, Galway, Ireland
Tel: +353 (0)91 774300 - Fax: +353 (0)91 774301

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Name:	Anne-Marie Keenan
Address:	Bio-Medical Research Ltd.,
	Parkmore Business Park, West
	Galway, Ireland
Telephone:	+353 91 774300
Fax:	+353 91 774302
E-Mail:	akeenan@bmr.ie
Prepared:	December 22, 2011

2. Device Name

Trade Name of Device:	Neurotech Recovery
Common Name:	Conductive Garment
Regulation Number:	21 CFR 882.1320
Regulation Name:	Cutaneous Electrode
Product Code:	GXY
Device Class:	2

3. Identification of Equivalent Legally Marketed Device

510(k) Number:	K070142
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	System-Abs
510(k) Number:	K082190
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	Baxolve XP Conductive Garment

K112934

4. Description of Device

The Neurotech Recovery is a non-sterile, reusable conductive garment for single patient use only. It acts as an interface between the adhesive electrodes on the patient's skin and the Neurotech Plus electrical stimulator which provides Neuromuscular Electrical Stimulation (NMES) or Transcutaneous Electrical Nerve Stimulation (TENS).

The Neurotech Recovery is available as two options, each targeting separate areas of the human anatomy;

1. The Neurotech Recovery for the lower back which is constructed of the following materials; Main Panels: 89% Nylon & 11% Spandex laminated to Polyurethane, Silver Trace, Binding: 100% Cotton & Hook and Loop Fastener: 100% Nylon
2. The Neurotech Recovery for the abdomen which is constructed of the following materials; Main Panels: 100% Nylon, Binding: 82% Nylon & 18% Elastane, Hook and Loop Fastener: 100% Nylon & Foam Padding: 100% Polyurethane

Included with each Neurotech Recovery conductive garment are conductive gel pads, an extender strap and instructions for use. The device is intended be available by prescription only.

5. Statement of Intended Use/Indications for Use

Intended Use:

The Neurotech Recovery is intended for home use. Sale of the device has been restricted to sale under a prescription order from a licensed practitioner.

Indications for Use:

The Neurotech Recovery – Back Conductive Garment for the back and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the low back.

The Neurotech Recovery – Back Conductive Garment for the abdomen and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the abdominal area.

K112934

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Neurotech Recovery device. No clinical tests have been submitted as part of this premarket notification. The Neurotech Plus device complies with the following international standards:

- I.S. EN ISO 14971 2007 Medical devices - Application of risk management to medical devices
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
- EN ISO 10993-10:2002 & Amendment 1 2006 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2002/Amd. 1:2006

Based on substantial equivalence analysis carried out between the proposed Neurotech Recovery device and the listed predicates, we believe that the proposed device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bio-Medical Research Ltd.
c/o Ms. Anne-Marie Keenan
Quality & Regulatory Engineer
Parkmore Business Park West
Galway,
Ireland

JAN 2 0 2012

Re: K112934
Trade/Device Name: Neurotech Recovery
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 21, 2011
Received: December 22, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112934

Device Name: Neurotech Recovery-Back

Indications for Use:

The Neurotech Recovery – Back Conductive Garment for the back and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the low back.

The Neurotech Recovery – Back Conductive Garment for the abdomen and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the abdominal area.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112934